

REMARKS/ARGUMENTS

The Examiner's attention to the present application is noted with appreciation.

All of the claims in the application have been cancelled and new claims have been introduced. The new claims clarify and more precisely define the invention but the clarification and definition is unrelated to patentability under 35 U.S.C. §§ 102, 103 and/or 112.

Applicant has made a number of changes to the specification to clarify the terminology used in the application and to correct certain typographical errors.

The Examiner had rejected original claims 13-16 and 19-22 under 35 U.S.C. § 102(e) as being anticipated by Weber (5,908,410). The following remarks relate to claims having similar subject matter. The Examiner has completely misunderstood either the invention or the teachings of Weber. Weber has nothing to do with immobilization and stereotactic localization of a patient's body for imaging and treatment. The Weber patent relates to catheters, or devices such as a stent, introduced into the body of the patient and having imaging markers for use with MRI. The purpose of the invention is to solve the problem as described in Column 1, lines 48-65 relating to the adverse affect on the nuclear magnetic field as a result of rotation or movement of the catheter during imaging. To solve the problem, the invention fits a catheter with an imaging marker that "produces an equal disturbance of the nuclear magnetic resonance field regardless of the position of the medical device relative to the magnetic resonance imaging equipment." (Column 2, lines 11-14) To solve the disturbance problem caused by the marker on an ordinary catheter, the markers (magnetic elements 35) are positioned on a helical path having a defined pitch whereby the position of the markers balance or cancel disturbance of the nuclear magnetic field. The Examiner has incorrectly identified the "reinforcing layer of wires 33, 34" (Column 5, lines 34-35) as "fiducials". The purpose of the wires is for "reinforcing" the mandrel; they are not fiducials in that they are not intentionally sensitive to the nuclear magnetic field for the purpose of localization. It is the "magnetic elements 35" (Column 5, lines 42-43) which are sensitive to the MRI field, but they are not "fiducials" used as a reference for an image, i.e., stereotactic localization.

It is therefore respectfully requested that the Examiner withdraw the objections based on Weber.

The Examiner has also rejected original claims 1, 3, 4, 6, 7, 9, 10, 12, 13-17 and 19-23 under 35 U.S.C. § 103 as unpatentable over Miller in view of Wessels. Contrary to the Examiner's description of Miller, it does not teach a method and apparatus of providing whole body localization. As made clear from the description of the entire apparatus and method in Applicant's application, localization refers to the use of imaging within a stereotactic space by employing fiducials for creating reference points on the images so as to enable the medical practitioner to precisely define the position of the lesion identified in the image relative to a point in stereotactic space by relating it to the fiducials. In the Miller method, while an x-ray is taken and the patient support is provided with radio opaque members, it is not for the purpose of

localization of the lesion relative to the radio opaque members which according to Miller generate "a registration grid on x-rays of the patient on the support". (Column 4, lines 52-53) The x-ray is used as made clear in the following discussion:

"Such x-rays taken after a patient has been repositioned on the support are compared with x-rays of the patient in the original supine position on the support. By comparing the x-ray the need for slight position adjustment is determined and by operation of the movable means 36, the patient is moved to the exact original supine position."

Thus, even assuming that the radio opaque members are in some sense "fiducials", the marker on the x-ray of such "fiducial" is in no manner related to the lesion. The x-ray including the "fiducial" is used to compare the original patient position with the subsequent position of the patient during a later treatment and adjusting the position of the patient in the latter event so that it conforms to the former event thereby providing the radiation to the same portion of the patient's anatomy. That is not localization as that term is used in the medical profession, in particular, medical practitioners using stereotactic devices, and even more particularly those stereotactic practitioners who utilize stereotactic space to reference the position of a lesion during treatment planning and subsequently treating the lesion using a stereotactic device. The Examiner has confused the concept of localization with immobilization. Localization requires immobilization, but immobilization alone does not constitute localization.

The Examiner admits that there are other deficiencies in Miller which the Examiner suggests would have been obvious to one of ordinary skill in the art to meet Applicant's invention. The Examiner admits that Miller does not teach the specific fiducial arrangement as taught by Applicant and relies upon Wessels which allegedly teaches various fiducial array patterns. Applicant disagrees that the "N" fiducial shown in Wessels is in any sense a "waveform" as that term is referred to in the patent and is now incorporated into new Claim 1. The concept of using an N-shaped fiducial in order to ascertain the axial position of a slice that is perpendicular to the two parallel fiducials has long been known in the art with respect to stereotactic head frames. Its use in a stereotactic body frame was an obvious adaptation of an N-shaped fiducial to another portion of the patient's body. However, as applicant points out, at page 15, "localization of a z position solely derived by the use of the slope of fiducial 5 is, therefore, not sufficiently accurate to precisely define a position for incremental changes of x." It is precisely this deficiency which Applicant overcame with the image resolver fiducial array. And it is this expression of the fiducial resolver

now set forth in the new claims -- at least one of the fiducials has a "trigonometric waveform" -- that clearly distinguishes the Wessels N-shaped fiducial array.

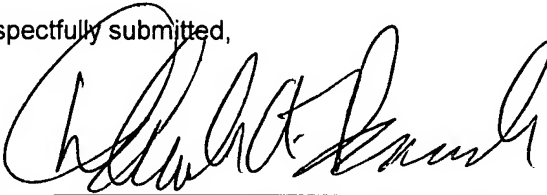
In addition to those arguments advanced above, it should be clear that the invention as a whole and all of the claims submitted are neither met by any one of the references relied upon by the Examiner nor any of those references in any combination. It is therefore respectfully submitted that new Claims 25 through 49 are patentable and a Notice of Allowance is respectfully requested.

In view of the above amendments and remarks, it is respectfully submitted that all grounds of rejection and objection have been avoided and/or traversed. It is believed that the case is now in condition for allowance and same is respectfully requested.

If any issues remain, or if the Examiner believes that prosecution of this application might be expedited by discussion of the issues, the Examiner is cordially invited to telephone the undersigned attorney for Applicant at the telephone number listed below.

Also being filed herewith is a Petition for Extension of Time to September 11, 2003, with the appropriate fee. Authorization is given to charge payment of any additional fees or claims fees required, or credit any overpayment, to Deposit Acct. 13-4213. A duplicate of this filing is provided for deposit account authority.

Respectfully submitted,



By:

Deborah A. Peacock, Reg. No. 31,649
Direct line: (505) 998-1501

PEACOCK, MYERS & ADAMS, P.C.
Attorneys for Applicant(s)
P.O. Box 26927
Albuquerque, New Mexico 87125-6927

Telephone: (505) 998-1500
Facsimile: (505) 243-2542

Customer No. 005179

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